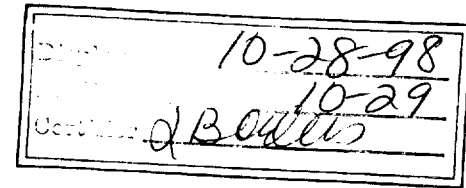


DMB



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 19, 1998, 8 a.m. to 6:30 p.m., and on November 20, 1998, 8 a.m. to 3:30 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

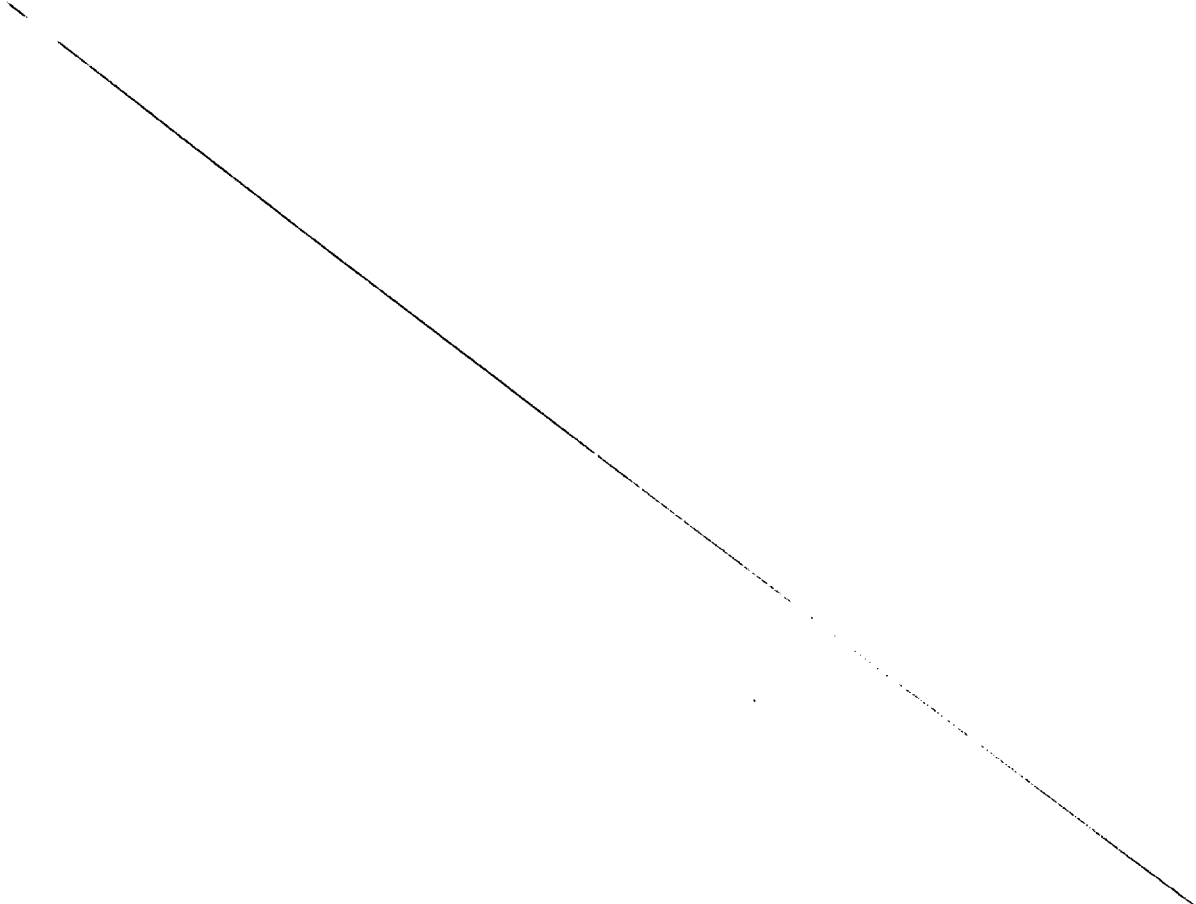
Contact Persons: Nancy T. Cherry or Denise H. Royster, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12391. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 19, 1998, the committee will discuss issues relating to the use of cell substrates. On November 20, 1998, the committee will discuss issues relating to the manufacture and safety of live attenuated influenza virus vaccines.

Procedure: On November 19, 1998, from 8 a.m. to 1:30 p.m., and on November 20, 1998, from 8 a.m. to 3:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written

submissions may be made to the contact persons by November 12, 1998. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:30 a.m. on November 19, 1998, and between approximately 8:15 a.m. and 8:30 a.m., and between approximately 10:20 a.m. and 10:50 a.m. on November 20, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 12, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On November 19, 1998, from 1:30 p.m. to 6:30 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). These portions of the meeting will be closed to discuss issues relating to pending or proposed investigational new drug applications.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.
2).

Dated: October 22, 1998



Michael A. Friedman
Deputy Commissioner for Operations

[FR Doc. 98-???? Filed ??-??-98; 8:45 am]

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